

1-17-95

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of ) Examiner: M. Thaler  
Paul G. Yock ) Group Art Unit: 3309  
For: ANGIOPLASTY APPARATUS )  
FACILITATING RAPID )  
EXCHANGES AND METHOD )  
Serial No.: 08/208,972 )  
Filed: March 9, 1994 )  
Matter No.: 18000.0029.0 )

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November 28, 1994

DECLARATION OF CARRIE BATES

The Commissioner  
United States Patent  
and Trademark Office  
Washington, DC 20231

Dear Sir:

I, Carrie Bates, depose and say that

1. I am Vice President of Marketing for Advanced Cardiovascular Systems, Inc. (ACS) and in my position as Vice President I am familiar with the sales volumes of ACS products as well as the sales volumes of competing products. I am also knowledgeable regarding the advertising of the various products sold by ACS.

2. On information and belief, the ACS products which are covered by the claims of the above application are the Elipse, ACS Flowtrack™ Dilatation Catheter, the ACS RX Perfusion™ Dilatation Catheter, the Streak dilatation catheter and the RX .014 dilatation catheter. The combined sales in the United States of the Elipse, the Flowtrack, the RX Perfusion, the Streak and the RX .014 dilatation catheters for the month of October 1994, the last month on which we have complete figures, represent about 29% of the total U.S. dilatation catheter market. The sales of the Elipse, the Flowtrack and the RX Perfusion are respectively the first, second and sixth highest sales of dilatation catheters in the United States.

3. On information and belief, rapid exchange dilatation catheters which are covered by the claims of the above application and sold by third parties include Schneider's MC Rail, Mongoose, Piccolino and Piccolino Forte 0.018; SciMed's Rally and Express; and Mansfield's Synergy. The sales of these catheters in total amount to about 12% of the total sales of dilatation catheters in the United States.

4. The total market for the above described rapid exchange type dilatation catheters is about 42% of the total market for dilatation catheters in the United States.

5. The advertising of the Elipse, the Flowtrack, the RX Perfusion Dilatation Catheter, and other ACS rapid exchange type

dilatation catheters has been directed to physicians who perform coronary angioplasty procedures, hospital and clinical personnel who purchase materials for such procedures and to other health care professions who are involved in coronary angioplasty procedures.

6. Advertising brochures which have been used for the Flowtrack and the RX Perfusion Dilatation Catheter and which exhibit typical advertising for these types of products are attached hereto.

7. As is evident in the attached advertising brochures, the advertising for such catheters is directed to the nature of the product and the advantages thereof and is addressed to health care professionals who are very knowledgeable about coronary balloon angioplasty.

8. The advertising brochures are distributed at seminars for physicians, nurses and other health care professionals involved with angioplasty procedures and at meetings of professional societies such as the American Heart Association and the American College of Cardiology.

9. No advertising for these catheters is directed to the public at large or to any group not involved with and knowledgeable about coronary heart disease.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with

the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

Date: 12/15/94

Carrie Bates  
Carrie Bates